

Chairman Dingell at the Subcommittee on Oversight and Investigations Hearing entitled, "Science and Mission at Risk: FDA's Self-Assessment"

Statement of Congressman John D. Dingell, Chairman
Committee on Energy and Commerce

SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS HEARING ENTITLED "SCIENCE AND MISSION AT RISK:
FDA'S SELF-ASSESSMENT"
January 29, 2008

Mr. Chairman, I commend you for holding today's hearing. As you stated earlier, the Food and Drug Administration (FDA) is now responsible for ensuring the safety of nearly a trillion dollars of products used by Americans every day. From medical devices, to food, to pharmaceuticals, and even pet food, each of us probably uses a product everyday that has been reviewed, studied, or regulated by the FDA.

Yet today, we will hear more bad news concerning the safety of these products. This morning, Congress and the American people will hear for the first time from a panel of world-renowned industry and academic experts who were directed by Commissioner Von Eschenbach to review the state of FDA. Their report includes many troubling findings about FDA, but most importantly, it concludes that the agency's mission is now at risk, which means the health and safety of Americans are at risk, as well. The Congress, the Food and Drug Commissioner, and the Administration must focus on these findings and find solutions quickly.

In December 2006, the FDA Commissioner requested that his Science Board form a special subcommittee to assess whether "science and technology" at the agency is capable of supporting existing and future regulatory operations.

This subcommittee had extensive input from 30 external advisors representing industry, academia, and other government agencies. These experts were chosen based on their extensive knowledge of cutting-edge research, budget, science, and management operations.

Their report is one of the most extensive reviews of FDA that I have seen, and we ought pay close attention to what these experts found.

Mr. Chairman, I think that the Nation owes gratitude to those who helped compile this report, and particularly to those who will testify today. Each of them committed substantial personal time to complete this report. The report is straightforward with findings that are difficult to face.

Their testimony, along with witnesses for the Government Accountability Office and Congressional Research Service, will describe an FDA that is struggling to keep the Nation's food and drug supply safe and effective. Specifically, they will describe:

- FDA's difficulties in inspecting the foreign manufacture of drugs and medical devices that are sold in the United States;

- FDA's faltering ability to enforce its own regulations and conduct rulemaking;
- FDA's substantially diminished capacity to inspect food production facilities, whether farms or processing plants;
- FDA's inadequate IT infrastructure that is antiquated, unstable, and incapable of supporting key agency missions; and finally
- FDA's lack of human and technological resources and its effect on its scientific capabilities.

Sadly, Mr. Chairman, many of these findings are not new to this Committee. This Subcommittee had more than five hearings alone last year documenting these persistent problems confronting FDA.

Our constituents are growing weary of these events. They are losing confidence in this agency's ability to protect them from the products they use daily.

I commend the Commissioner for requesting this review and I look forward to his testimony about his proposals to fix this agency. FDA, HHS, and the Administration must address these failures and work with the Congress to develop a real plan to strengthen FDA and ensure its ability to carry out its critical mission for the people of this Nation.

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